



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,095	04/04/97	NELSON	R

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18M2/0106

EXAMINER  
WITZ, J

ART UNIT	PAPER NUMBER
1808	2

DATE MAILED:

01/06/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/33,096

Applicant(s)  
Nelson et al.

Examiner  
Sean C. Witz

Group Art Unit  
1808



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-66 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 22, 23, 34-43, 46-48, and 52-62 is/are allowed.
- ☒ Claim(s) 1-21, 24-33, 44, 45, 49-51, and 63-66 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Seria Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Priority*

1. Applicants are requested to update the status of the applications listed for priority under 35 USC 120.

### *Claim Rejections - 35 USC § 112*

2. Claims 63-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising deproteinated fasting bear serum or urine and the fractions disclosed in the specification, does not reasonably provide enablement for a pharmacological composition comprising 24,25-dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While applicants show the effects of the deproteinated fasting bear serum or urine, it is unclear and not predictable that 24,25-dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less are the active ingredients responsible for the bone formation, especially in view of the wide and varied quantity and quality of the components of the individual fractions of the deproteinated serum or urine. One skilled in the art would be unable to predict that isolation

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of merely the above referenced components would result in the desired stimulation of bone formation.

3. Claims 1-21, 24-30, 44-45 and 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, the phrase "having the characteristics"" fails to distinctly describe the composition, as it is unclear to what characteristics the phrase such that the metes and bounds of the claims are not clear. In the claims, it is unclear what is meant by the term "ursus-like". Further, the phrase "resembling the characteristics of a bear derived isolate" fails to distinctly describe the composition, as it is unclear what constitute "resembling" and a "bear derived isolate". In claim 4, it is unclear what is meant by the phrase "at least one vital sign of behavioral modification substance"; further, it is not clear what is meant by the term "metabolites". In claim 8, it is not clear what is meant by the phrase "having the characteristics of an isolate of whole blood or whole urine sample". In claims 10 and 11, the phrase "having the characteristics of the deproteinated urine or blood serum isolate of fasting bear" is unclear. In claims 12-15, the term "substance" is unclear; use of statutory language "composition" or "compound" is suggested. In claim 12, the phrase "having the characteristics of a sample of whole blood or whole urine taken from a fasting black bear" is also unclear. In claim 13, it is unclear what is meant by the term "signature exhibited in the deproteinated isolate of urine or blood". Claims 1-15 and 18 are deemed vague and indefinite as the claims are defined by functional language; the

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claims are defined by what the composition does and not by what it is. Further, comparisons by use of the phrase "having the characteristics" are vague as there is no way to determine the required characteristics of the compared "isolate". Also, there is no preamble language and no transitional phrasing. It is unclear as to exactly what Applicants consider their invention. In claim 17, the term "derived" is unclear; use of the term "obtained" is suggested. Further, there is no transitional phrasing so that the metes and bounds of the claims are unclear; this is true also for claims 18 and 19. In claims 44 and 45, it is unclear what is comprised by the term "active substance".

#### *Double Patenting*

4. Claims 32-33, 49 and 51 are rejected under 35 U.S.C. 101 as being a substantial duplicate of claims 31, 48 and 50, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

#### *Allowable Subject Matter*

5. Claims 22-23, 31, 34-43, 46-48 and 52-62 are allowed.

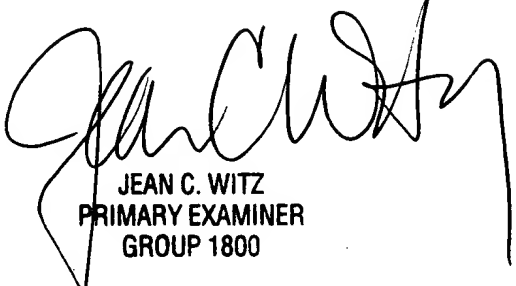
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

January 5, 1998



JEAN C. WITZ  
PRIMARY EXAMINER  
GROUP 1800

3 FILES SEARCHED...  
L1 0 (SERUM OR BLOOD OR URINE) (5A) ((FASTING OR DENNING) (3A)  
BEAR)